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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,811	05/16/2006	Gilad Lerman	36048/US/2-475396-00173	5970
30873 7590 03/17/2011 DORSEY & WHITNEY LLP - NEW YORK (PT/18) ATTENTION: INTELLECUAL PROPERTY/PATENT DEPARTMENT 250 PARK AVENUE NEW YORK, NY 10177-1500				
EXAMINER BEGIN, RUSSELL SCOTT				
ART UNIT		PAPER NUMBER		
1631				
NOTIFICATION DATE		DELIVERY MODE		
03/17/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/579,811

Applicant(s)

LERMAN ET AL.

Examiner

Russell S. Negin

Art Unit

1631

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 25-27, 37-43 and 45-64 is/are pending in the application.
- 4a) Of the above claim(s) 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 25-27, 37-39, 43 and 45-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Comments

Applicant's amendments and request for reconsideration in the communication filed on 27 December 2010 are acknowledged and the amendments are entered.

Claims 40-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10 December 2008.

Claims 1-3, 25-27, 37-43, and 45-64 are pending in the instant application.

Claims 1-3, 25-27, 37-39, 43, and 45-64 are examined in this Office action.

Withdrawn Rejections

The rejections of claim 25-27, 45, and 55-62 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter are withdrawn in view of amendments filed to the instant set of claims on 27 December 2010.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection is reiterated:

Claims 1-3, 25-27, 37-39, 43, and 45-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delenstarr et al. [Proceedings of the SPIE, 2001, volume 4266, pages 120-131] as evidenced by Z-score [The Concise Corsini Encyclopedia of Psychology and Behavioral Science, 2004] in view of Lincoln et al. [WO 99/49403; published 30 September 1999].

Independent claim 1 is drawn to a process for determining statistically-outlying data points in at least one dataset. The method comprises receiving the at least one dataset. The method additionally comprises determining at least one interval associated with the dataset. The method additionally comprises using a hardware processing arrangement (comprising a processor) for determining a plurality of subintervals of the at least one interval by repeatedly dividing the interval until at least one predetermined criteria is met. The method additionally comprises determining the

statistically-outlying data points present in the at least one dataset based on information related to the sub-intervals, wherein each particular data point of the statistically outlying data points is both associated with a particular subinterval and determined as a function of a length of this subinterval.

Independent claim 25 is drawn to similar subject matter as claim 1 except it is drawn to a storage medium comprising software that executes similar limitations on computer hardware.

Independent claim 37 is drawn to similar subject matter as claim 1 except it is drawn to a system for determining statistically-outlying data points comprising using a processor.

The article of Delenstarr et al. studies estimation of the confidence limits of oligonucleotide array-based measurements of differential expression [title]. Specifically, the objective of Delenstarr et al. is to analyze error in the form of outlying data as a result of differential expression of mRNAs in two samples. Figure 1 on page 125 of Delenstarr et al. illustrates the receiving of at least one dataset. The abscissa axes of Figure 1b of Delenstarr et al. illustrate the intervals associated with each of the red and green channels. This interval is broken down into subintervals in the form of widths of histogram bars. In other words, the intervals of Figure 1b of Delenstarr et al. are divided into subintervals until the criterion of the entire histogram being displayed with the bars of the given width is met. The data within the histograms are considered to be outlying data if the histogram bar is more than two standard deviations away on either side on the mean [last full paragraph of page 121 of Delenstarr et al.]. Consequently, in

determining whether a histogram bar corresponds to an outlier, the data point is associated with the subinterval that encompasses it, which, in turn, is determined as a function of length from the mean (in this instance, length is the number of standard deviations from the mean).

While Delenstarr et al. teaches the software to analyze images [paragraph bridging pages 120-121 of Delenstarr et al.], Delenstarr et al. does not teach all of the computer limitations of the instantly rejected claims.

The document of Lincoln et al. studies a system and method of analyzing biomolecular sequences by placing them into bins wherein each bin corresponds to a consensus sequence of the biopolymer. Figure 19 of Lincoln et al. is an example of this fitting of polymer data into bins. Furthermore, Figure 4B of Lincoln et al. illustrates the computer media and computer hardware components for binning the polymeric data.

With regard to claims 2 and 26, the two plots in Figure 1b of Delenstarr et al. are as a result of either using green or red channels (two conditions).

With regard to claims 3 and 27, the green and red in the plots of Figure 1b of Delenstarr et al. reflect a mutational process of using the different labels (i.e. Cy3-CTP vs. Cy5-CTP) discussed in the paragraph bridging pages 120-121 of Delenstarr et al.

With regard to claim 38, Figure 4B of Lincoln et al. illustrates a hardware processing arrangement comprising a processor. With regard to claim 39, the plurality

of signals in Figure 1b of Delenstarr et al. are the red and green signals indicative of gene expression converted into two datasets.

With regard to claim 43 and 45-46, Figure 1b of Delenstarr et al. illustrates the statistically outlying points in a user readable format. Figure 4B of Lincoln et al. illustrates the storage of binned data in a user-accessible format.

With regard to claims 47-48 and 55-56, the predetermined criteria for the portion of the dataset being contained in an outlying subinterval is if the portion of the dataset in the subinterval is at least two standard deviations from the mean (Figure 1b of Delenstarr et al.). As the Z-score reference teaches, data greater than two standard deviations from the mean form a fixed ratio/percentage of the entire dataset.

With regard to claims 49 and 57, Figure 1a of Delenstarr et al. teaches the raw data in the form of a dyadic grid that are processed into the histogram of Figure 1b of Delenstarr et al.

With regard to claims 50-54 and 58-64, the determination of outliers in Figure 1b of Delenstarr et al. is based on whether the subinterval is greater than two standard deviations from the mean on the principal (abscissa) axis. Consequently, the portion of data that is greater than two standard deviations in length from the mean is considered to be outlying data. It is noted that this measure of two standard deviations is not only a

length, but it is also (as defined in Z-score) a ratio of a number of outliers to a number of normal points such that for a fixed number of points within two standard deviations from means, there are a deducible number of outlying points. It is also noted that each of the bars in the histogram has a height that is a function of length/position on the abscissa.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the estimation of outlying biological data in gene expression in Delenstarr et al. by use of the computer hardware of Lincoln et al. wherein the motivation would have been that automation of the procedure of deducing outlying points expedites and increases the efficiency of processing [Figure 4B of Lincoln et al.]. There would have been a reasonable expectation of success in combining Delenstarr et al. with Lincoln et al. because both studies analogously apply to analyzing biological data that is binned.

Response to Arguments

Applicant's arguments filed 27 December 2010 have been fully considered but they are not persuasive.

Applicant first argues on page 20 of the Remarks that the histograms of Figure 1b of Delenstarr et al. are not equivalent to the intervals and subintervals recited in the instantly rejected claims. This argument is not persuasive because the result of using the green channel in Figure 1b of Delenstarr et al. (top plot) is a plot of bars of data (subintervals) of equal width within the interval between 1020 and 1180 counts.

Likewise, the result of using the red channel in Figure 1b of Delenstarr et al. (bottom plot) is a plot of bars of data (subintervals) of equal width within the interval between 1000 and 1600 counts.

Applicant next argues on page 20 of the Remarks that the histograms of Figure 1b of Delenstarr et al. represent two separate histograms of signals (one for the green channel and the second for the red channel) representing pixel data. While this observation may be true, it does not support any notion that Delenstarr et al. does not teach the proper claim limitations. Conversely, Delenstarr et al. teaches the proper claim limitations independently two times: once for the green channel, and next for the red channel).

Applicant next argues on pages 20-21 of the Remarks that the histograms of Figure 1b of Delenstarr et al. do not repeatedly divide an interval into subintervals. This argument is not persuasive because each of the histograms in Figure 1b of Delenstarr et al. takes an interval (1020 cts to 1180 cts for the green channel and 1000 cts to 1600 cts for the red channel) and then divides or "bins" the intervening data into roughly equal subintervals within the green or red channel data. In other words, without repeatedly dividing the range of the abscissa into smaller bars, each of the two plots would consist of a non-informative single bar from 1020 cts to 1180 cts for the green channel and a non-informative single bar from 1000 cts to 1600 cts for the red channel.

Applicant next argues the following on page 21 of the Remarks:

Applicants respectfully assert that the Examiner's contention in the Office Action that the "length [of a particular subinterval] is the number of standard deviations from the mean" is *nonsensical*, and *counter* to the Examiner's contention in the same paragraph...

While it is agreed that this remark is valid as stated, applicant is taking the statements from the Office action out of context (and even inserting unintended phrases into this citation from the Office action) to make this argument. Each independent claim recites that each data point of the statistically outlying data points is "determined as a function of a length of the particular subinterval of the subintervals associated with the particular data point." These claims do ***NOT*** recite that each data point of the statistically outlying data points is "determined as a function of the length of the particular subinterval of the subintervals associated with the particular data point." Consequently, since the length between the mean and the subinterval (i.e. bar) on the abscissa of the histogram is a length of the particular subinterval, Delenstarr et al. teaches this limitation of the independent claims. It is further noted that there is no disclosure in the specification defining a length of a subinterval to be limited to the length of the subinterval.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Russell S. Negin/
Primary Examiner, Art Unit 1631
11 March 2011